

**House File 597 - Introduced**

HOUSE FILE 597  
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 200)

**A BILL FOR**

1 An Act creating new procedures for external review of health  
2 care coverage decisions by health carriers and including  
3 transition and applicability provisions.  
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514J.101 Purpose — applicability.

2 The purpose of this chapter is to provide uniform standards  
3 for the establishment and maintenance of external review  
4 procedures to assure that covered persons have the opportunity  
5 for an independent review of an adverse determination or final  
6 adverse determination made by a health carrier as required  
7 by the federal Patient Protection and Affordable Care Act,  
8 Pub. L. No. 111-148, as amended by the federal Health Care and  
9 Education Reconciliation Act of 2010, Pub. L. No. 111-152,  
10 which amends the Public Health Service Act and adopts, in part,  
11 new 42 U.S.C. § 300gg-19, and to address issues which are  
12 unique to the external review process in this state.

13 Sec. 2. NEW SECTION. 514J.102 Definitions.

14 As used in this chapter, unless the context otherwise  
15 requires:

16 1. "*Adverse determination*" means a determination by a health  
17 carrier that an admission, availability of care, continued  
18 stay, or other health care service that is a covered benefit  
19 has been reviewed and, based upon the information provided,  
20 does not meet the health carrier's requirements for medical  
21 necessity, appropriateness, health care setting, level of care,  
22 or effectiveness, and the requested service or payment for the  
23 service is therefore denied, reduced, or terminated. "*Adverse*  
24 *determination*" does not include a denial of coverage for a  
25 service or treatment specifically listed in plan or evidence  
26 of coverage documents as excluded from coverage, or a denial  
27 of coverage for a service or treatment that has already been  
28 received and for which the covered person has no financial  
29 liability.

30 2. "*Authorized representative*" means any of the following:

31 a. A person to whom a covered person has given express  
32 written consent to represent the covered person in an external  
33 review.

34 b. A person authorized by law to provide substituted consent  
35 for a covered person.

1 c. A family member of the covered person when the covered  
2 person is unable to provide consent.

3 d. The covered person's treating health care professional  
4 when the covered person is unable to provide consent.

5 3. "*Best evidence*" means evidence based on randomized  
6 clinical trials. If randomized clinical trials are not  
7 available, "*best evidence*" means evidence based on cohort  
8 studies or case-control studies. If randomized clinical  
9 trials, cohort studies, or case-control studies are not  
10 available, "*best evidence*" means evidence based on case-series  
11 studies. If none of these are available, "*best evidence*" means  
12 evidence based on expert opinion.

13 4. "*Case-control study*" means a retrospective evaluation  
14 of two groups of patients with different outcomes to determine  
15 which specific interventions the patients received.

16 5. "*Case-series study*" means an evaluation of a series  
17 of patients with a particular outcome, without the use of a  
18 control group.

19 6. "*Certification*" means a determination by a health carrier  
20 that an admission, availability of care, continued stay, or  
21 other health care service has been reviewed and, based on  
22 the information provided, satisfies the health carrier's  
23 requirements for medical necessity, appropriateness, health  
24 care setting, level of care, and effectiveness.

25 7. "*Clinical review criteria*" means the written screening  
26 procedures, decision abstracts, clinical protocols, and  
27 practice guidelines used by a health carrier to determine the  
28 necessity and appropriateness of health care services.

29 8. "*Cohort study*" means a prospective evaluation of two  
30 groups of patients with only one group of patients receiving a  
31 specific intervention.

32 9. "*Commissioner*" means the commissioner of insurance.

33 10. "*Covered benefits*" or "*benefits*" means those health care  
34 services to which a covered person is entitled under the terms  
35 of a health benefit plan.

1 11. "*Covered person*" means a policyholder, subscriber,  
2 enrollee, or other individual participating in a health benefit  
3 plan.

4 12. "*Disclose*" means to release, transfer, or otherwise  
5 divulge protected health information to any person other than  
6 the individual who is the subject of the protected health  
7 information.

8 13. "*Emergency medical condition*" means the sudden and, at  
9 the time, unexpected onset of a health condition or illness  
10 that requires immediate medical attention, where failure to  
11 provide medical attention would result in a serious impairment  
12 to bodily functions, serious dysfunction of a bodily organ or  
13 part, or would place the person's health in serious jeopardy.

14 14. "*Emergency services*" means health care items and  
15 services furnished or required to evaluate and treat an  
16 emergency medical condition.

17 15. "*Evidence-based standard*" means the conscientious,  
18 explicit, and judicious use of the current best evidence based  
19 on the overall systematic review of the research in making  
20 decisions about the care of individual patients.

21 16. "*Expert opinion*" means a belief or an interpretation  
22 by specialists with experience in a specific area about  
23 the scientific evidence pertaining to a particular service,  
24 intervention, or therapy.

25 17. "*Facility*" means an institution providing health  
26 care services or a health care setting, including but not  
27 limited to hospitals and other licensed inpatient centers,  
28 ambulatory surgical or treatment centers, skilled nursing  
29 centers, residential treatment centers, diagnostic, laboratory  
30 and imaging centers, and rehabilitation and other therapeutic  
31 health settings.

32 18. "*Final adverse determination*" means an adverse  
33 determination involving a covered benefit that has been upheld  
34 by a health carrier at the completion of the health carrier's  
35 internal grievance process.

1 19. *"Health benefit plan"* means a policy, contract,  
2 certificate, or agreement offered or issued by a health carrier  
3 to provide, deliver, arrange for, pay for, or reimburse any of  
4 the costs of health care services.

5 20. *"Health care professional"* means a physician or other  
6 health care practitioner licensed, accredited, registered, or  
7 certified to perform specified health care services consistent  
8 with state law.

9 21. *"Health care provider"* or *"provider"* means a health care  
10 professional or a facility.

11 22. *"Health care services"* means services for the diagnosis,  
12 prevention, treatment, cure, or relief of a health condition,  
13 illness, injury, or disease.

14 23. *"Health carrier"* means an entity subject to the  
15 insurance laws and regulations of this state, or subject  
16 to the jurisdiction of the commissioner, including an  
17 insurance company offering sickness and accident plans, a  
18 health maintenance organization, a nonprofit health service  
19 corporation, a plan established pursuant to chapter 509A  
20 for public employees, or any other entity providing a plan  
21 of health insurance, health care benefits, or health care  
22 services. *"Health carrier"* includes, for purposes of this  
23 chapter, an organized delivery system.

24 24. *"Health information"* means information or data, whether  
25 oral or recorded in any form or medium, and personal facts or  
26 information about events or relationships that relates to any  
27 of the following:

28 a. The past, present, or future physical, mental, or  
29 behavioral health or condition of a covered person or a member  
30 of the covered person's family.

31 b. The provision of health care services to a covered  
32 person.

33 c. Payment to a health care provider for the provision of  
34 health care services to a covered person.

35 25. *"Independent review organization"* means an entity that

1 conducts independent external reviews of adverse determinations  
2 and final adverse determinations.

3 26. "*Medical or scientific evidence*" means evidence found in  
4 any of the following sources:

5 a. Peer-reviewed scientific studies published in or accepted  
6 for publication by medical journals that meet nationally  
7 recognized requirements for scientific manuscripts and that  
8 submit most of their published articles for review by experts  
9 who are not part of the editorial staff.

10 b. Peer-reviewed medical literature, including literature  
11 relating to therapies reviewed and approved by a qualified  
12 institutional review board, biomedical compendia, and other  
13 medical literature that meet the criteria of the national  
14 institutes of health's national library of medicine for  
15 indexing in index medicus or medline, or of elsevier science  
16 ltd. for indexing in excerpta medicus or embase.

17 c. Medical journals recognized by the United States  
18 secretary of health and human services under section 1861(t)(2)  
19 of the federal Social Security Act.

20 d. The following standard reference compendia:

21 (1) American hospital formulary service drug information.

22 (2) Drug facts and comparisons.

23 (3) American dental association accepted dental  
24 therapeutics.

25 (4) United States pharmacopoeia drug information.

26 e. Findings, studies, or research conducted by or under  
27 the auspices of federal government agencies and nationally  
28 recognized federal research institutes, including any of the  
29 following:

30 (1) Federal agency for health care research and quality.

31 (2) National institutes of health.

32 (3) National cancer institute.

33 (4) National academy of sciences.

34 (5) Centers for Medicare and Medicaid services.

35 (6) Federal food and drug administration.

1 (7) Any national board recognized by the national  
2 institutes of health for the purpose of evaluating the medical  
3 value of health care services.

4 f. Any other medical or scientific evidence that is  
5 comparable to the sources listed in paragraphs "a" through "e".

6 27. "NAIC" means the national association of insurance  
7 commissioners.

8 28. "*Organized delivery system*" means an entity system  
9 authorized under 1993 Iowa Acts, ch. 158, and licensed by the  
10 director of public health, and performing utilization review.

11 29. "*Person*" means an individual, a corporation, a  
12 partnership, an association, a joint venture, a joint stock  
13 company, a trust, an unincorporated organization, any similar  
14 entity, or any combination of the foregoing.

15 30. "*Protected health information*" means health information  
16 that meets either of the following descriptions:

17 a. Health information that identifies a covered person who  
18 is the subject of the information.

19 b. Health information with respect to which there is a  
20 reasonable basis to believe that the information could be used  
21 to identify a covered person.

22 31. "*Randomized clinical trial*" means a controlled,  
23 prospective study of patients that have been randomized into an  
24 experimental group and a control group at the beginning of the  
25 study with only the experimental group of patients receiving a  
26 specific intervention, which includes study of the groups for  
27 variables and anticipated outcomes over time.

28 Sec. 3. NEW SECTION. 514J.103 **Applicability and scope.**

29 1. Except as provided in subsection 2, this chapter shall  
30 apply to all health carriers.

31 2. This chapter shall not apply to any of the following:

32 a. A policy or certificate that provides coverage only for a  
33 specified disease, specified accident or accident-only, credit,  
34 disability income, hospital indemnity, long-term care, dental  
35 care, vision care, or any other limited supplemental benefit.

1     *b.* A Medicare supplement policy of insurance, as defined by  
2 the commissioner by rule.

3     *c.* Coverage under a plan through Medicare, Medicaid, or the  
4 federal employees health benefits program, any coverage issued  
5 under 10 U.S.C. ch. 55, and any coverage issued as supplemental  
6 to that coverage.

7     *d.* Any coverage issued as supplemental to liability  
8 insurance.

9     *e.* Workers' compensation or similar insurance.

10    *f.* Automobile medical-payment insurance or any insurance  
11 under which benefits are payable with or without regard to  
12 fault, whether written on a group blanket or individual basis.

13    Sec. 4. NEW SECTION. 514J.104 **Notice of right to external**  
14 **review.**

15    1. A health carrier shall notify a covered person or the  
16 covered person's authorized representative, if known, in  
17 writing of the covered person's right to request an external  
18 review and include the appropriate statements and information  
19 set forth in this chapter at the time the health carrier sends  
20 written notice of a final adverse determination.

21    2. *a.* The notice shall include the following, or  
22 substantially equivalent, language:

23    We have denied your request for the provision of or payment  
24 for a health care service or course of treatment. You may  
25 have the right to have our decision reviewed by health care  
26 professionals who have no association with us if our decision  
27 involved making a judgment as to the medical necessity,  
28 appropriateness, health care setting, level of care, or  
29 effectiveness of the health care service or treatment you  
30 requested by submitting a request for external review to the  
31 commissioner of insurance.

32    *b.* The notice shall include the current address and contact  
33 information for the commissioner as specified in administrative  
34 rule.

35    3. The health carrier shall include in the notice a

1 statement informing the covered person or the covered person's  
2 authorized representative, if known, of the following:

3     *a.* If the covered person has a medical condition pursuant  
4 to which the time frame for completion of a standard external  
5 review would seriously jeopardize the life or health of the  
6 covered person or would jeopardize the covered person's ability  
7 to regain maximum function, the covered person or the covered  
8 person's authorized representative may file a request for an  
9 expedited external review.

10     *b.* If the final adverse determination concerns an admission,  
11 availability of care, continued stay, or health care service  
12 for which the covered person received emergency services, but  
13 has not been discharged from a facility, the covered person or  
14 the covered person's authorized representative may request an  
15 expedited external review.

16     *c.* If the final adverse determination concerns a denial  
17 of coverage based on a determination that the recommended or  
18 requested health care service or treatment is experimental  
19 or investigational as provided in section 514J.109, and the  
20 covered person's treating health care professional certifies  
21 in writing that the recommended or requested health care  
22 service or treatment that is the subject of the recommendation  
23 or request would be significantly less effective if not  
24 promptly initiated, the covered person or the covered person's  
25 authorized representative may request an expedited external  
26 review.

27     4. The health carrier shall include with the notice a copy  
28 of the descriptions of both the standard and expedited external  
29 review procedures the health carrier is required to provide  
30 pursuant to section 514J.116, highlighting the provisions in  
31 the external review procedures that give the covered person or  
32 the covered person's authorized representative the opportunity  
33 to submit additional information and including any forms used  
34 to process an external review.

35     5. The health carrier shall also include with the notice

1 an authorization form, or other document approved by the  
2 commissioner that complies with the requirements of 45 C.F.R.  
3 § 164.508 and with Tit. I of the federal Genetic Information  
4 Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat.  
5 881, by which the covered person or the covered person's  
6 authorized representative authorizes the health carrier and  
7 the covered person's treating health care provider to disclose  
8 protected health information, including medical records,  
9 concerning the covered person that is pertinent to the external  
10 review.

11 Sec. 5. NEW SECTION. 514J.105 **Request for external review.**

12 A covered person or the covered person's authorized  
13 representative may make a request for an external review of  
14 a final adverse determination. Except for a request for an  
15 expedited external review, all requests for external review  
16 shall be made in writing to the commissioner. The commissioner  
17 may prescribe by rule the form and content of external review  
18 requests.

19 Sec. 6. NEW SECTION. 514J.106 **Exhaustion of internal  
20 grievance process — exceptions — expedited external review  
21 request.**

22 1. Except as otherwise provided in this section, a request  
23 for an external review shall not be made until the covered  
24 person or the covered person's authorized representative has  
25 exhausted the health carrier's internal grievance process and  
26 received a final adverse determination.

27 2. A covered person or the covered person's authorized  
28 representative shall be considered to have exhausted the health  
29 carrier's internal grievance process if the covered person or  
30 the covered person's authorized representative has filed a  
31 grievance involving an adverse determination and, except to the  
32 extent the covered person or the covered person's authorized  
33 representative requested or agreed to a delay, has not received  
34 a written decision on the grievance from the health carrier  
35 within thirty days following the date the covered person or the

1 covered person's authorized representative filed the grievance  
2 with the health carrier.

3 3. A covered person or the covered person's authorized  
4 representative may file a request for an expedited external  
5 review of an adverse determination without exhausting the  
6 health carrier's internal grievance process under either of the  
7 following circumstances:

8 a. The covered person has a medical condition pursuant  
9 to which the time frame for completion of an internal review  
10 of the grievance involving an adverse determination would  
11 seriously jeopardize the life or health of the covered person  
12 or would jeopardize the covered person's ability to regain  
13 maximum function as provided in section 514J.108.

14 b. The adverse determination involves a denial of  
15 coverage based on a determination that the recommended or  
16 requested health care service or treatment is experimental or  
17 investigational and the covered person's treating physician  
18 certifies in writing that the recommended or requested health  
19 care service or treatment that is the subject of the adverse  
20 determination would be significantly less effective if not  
21 promptly initiated as provided in section 514J.109.

22 4. A request for an external review of an adverse  
23 determination may be made before the covered person or the  
24 covered person's authorized representative has exhausted the  
25 health carrier's internal grievance procedures whenever the  
26 health carrier agrees to waive the exhaustion requirement.  
27 If the requirement to exhaust the health carrier's internal  
28 grievance procedures is waived, the covered person or the  
29 covered person's authorized representative may file a request  
30 with the commissioner in writing for a standard external  
31 review.

32 **Sec. 7. NEW SECTION. 514J.107 External review — standard.**

33 1. A covered person or the covered person's authorized  
34 representative may file a written request for an external  
35 review with the commissioner within four months after any of

1 the following events:

2     *a.* The date of receipt of a final adverse determination.

3     *b.* The failure of a health carrier to issue a written  
4 decision within thirty days following the date the covered  
5 person or the covered person's authorized representative filed  
6 a grievance involving an adverse determination as provided in  
7 section 514J.106, subsection 2.

8     *c.* The agreement of the health carrier to waive the  
9 requirement that the covered person or the covered person's  
10 authorized representative exhaust the health carrier's internal  
11 grievance procedures before filing a request for external  
12 review of an adverse determination as provided in section  
13 514J.106, subsection 4.

14     2. Within one business day after the date of receipt of a  
15 request for external review, the commissioner shall send a copy  
16 of the request to the health carrier.

17     3. Within five business days following the date of receipt  
18 of the external review request from the commissioner, the  
19 health carrier shall complete a preliminary review of the  
20 request to determine whether:

21     *a.* The individual is or was a covered person under the  
22 health benefit plan at the time the health care service was  
23 recommended or requested.

24     *b.* The health care service that is the subject of the  
25 adverse determination or of the final adverse determination,  
26 is a covered service under the covered person's health benefit  
27 plan, but for a determination by the health carrier that the  
28 health care service is not covered because it does not meet  
29 the health carrier's requirements for medical necessity,  
30 appropriateness, health care setting, level of care, or  
31 effectiveness.

32     *c.* The covered person or the covered person's authorized  
33 representative has exhausted the health carrier's internal  
34 grievance process, unless the covered person or the covered  
35 person's authorized representative is not required to exhaust

1 the health carrier's internal grievance process pursuant to  
2 section 514J.106 or this section.

3 *d.* The covered person or the covered person's authorized  
4 representative has provided all the information and forms  
5 required to process an external review request.

6 4. Within one business day after completion of a preliminary  
7 review pursuant to subsection 3, the health carrier shall  
8 notify the commissioner and the covered person or the covered  
9 person's authorized representative in writing whether the  
10 request is complete and whether the request is eligible for  
11 external review.

12 *a.* If the health carrier determines that the request is not  
13 complete, the health carrier shall notify the covered person  
14 or the covered person's authorized representative and the  
15 commissioner in writing that the request is not complete and  
16 what information or materials are needed to make the request  
17 complete.

18 *b.* If the health carrier determines that the request is  
19 not eligible for external review, the health carrier shall  
20 issue a notice of initial determination in writing informing  
21 the covered person or the covered person's authorized  
22 representative and the commissioner of that determination  
23 and the reasons the request is not eligible for review. The  
24 health carrier shall also include a statement in the notice  
25 informing the covered person or the covered person's authorized  
26 representative that the health carrier's initial determination  
27 of ineligibility may be appealed to the commissioner.

28 5. The commissioner may specify by rule the form required  
29 for the health carrier's notice of initial determination and  
30 any supporting information to be included in the notice.

31 6. The commissioner may determine that a request is eligible  
32 for external review, notwithstanding a health carrier's initial  
33 determination that the request is not eligible, and refer the  
34 request for external review. In making this determination, the  
35 commissioner's decision shall be made in accordance with the

1 terms of the covered person's health benefit plan and shall be  
2 subject to all applicable provisions of this chapter.

3 7. Within one business day after receipt of notice from  
4 a health carrier that a request for external review is  
5 eligible for external review or upon a determination by the  
6 commissioner that a request is eligible for external review,  
7 the commissioner shall do all of the following:

8 a. Assign an independent review organization from the list  
9 of approved independent review organizations maintained by the  
10 commissioner and notify the health carrier of the name of the  
11 assigned independent review organization. The assignment of  
12 an independent review organization shall be done on a random  
13 basis among those approved independent review organizations  
14 qualified to conduct the particular external review based on  
15 the nature of the health care service that is the subject of  
16 the adverse determination or final adverse determination and  
17 other circumstances, including conflict of interest concerns.

18 b. Notify the covered person or the covered person's  
19 authorized representative in writing that the request is  
20 eligible and has been accepted for external review including  
21 the name of the assigned independent review organization and  
22 that the covered person or the covered person's authorized  
23 representative may submit in writing to the independent review  
24 organization within five business days following receipt of  
25 such notice from the commissioner, additional information  
26 that the independent review organization shall consider  
27 when conducting the external review. The independent review  
28 organization may, in the organization's discretion, accept and  
29 consider additional information submitted by the covered person  
30 or the covered person's authorized representative after five  
31 business days.

32 8. Within five business days after receipt of notice from  
33 the commissioner pursuant to subsection 7, the health carrier  
34 shall provide to the independent review organization the  
35 documents and any information considered in making the adverse

1 determination or final adverse determination. Failure by the  
2 health carrier to provide the documents and information within  
3 the time specified shall not delay the conduct of the external  
4 review.

5 9. If the health carrier fails to provide the documents  
6 and information within the time specified, the independent  
7 review organization may terminate the external review and  
8 make a decision to reverse the adverse determination or final  
9 adverse determination. Within one business day after making  
10 such a decision, the independent review organization shall  
11 notify the covered person or the covered person's authorized  
12 representative, the health carrier, and the commissioner of its  
13 decision.

14 10. The independent review organization shall review  
15 all of the information and documents received pursuant to  
16 subsection 8 and any other information submitted in writing  
17 to the independent review organization by the covered person  
18 or the covered person's authorized representative pursuant to  
19 subsection 7, paragraph "b". Upon receipt of any information  
20 submitted by the covered person or the covered person's  
21 authorized representative, the independent review organization  
22 shall, within one business day, forward the information to the  
23 health carrier. In reaching a decision the independent review  
24 organization is not bound by any decisions or conclusions  
25 reached during the health carrier's internal grievance process.

26 11. Upon receipt of information forwarded pursuant to  
27 subsection 10, a health carrier may reconsider its adverse  
28 determination or final adverse determination that is the  
29 subject of the external review.

30 a. Reconsideration by the health carrier of its  
31 determination shall not delay or terminate the external review.  
32 The external review shall only be terminated if the health  
33 carrier decides, upon completion of its reconsideration, to  
34 reverse its determination and provide coverage or payment for  
35 the health care service that is the subject of the adverse

1 determination or final adverse determination.

2     *b.* Within one business day after making a decision  
3 to reverse its adverse determination or final adverse  
4 determination, the health carrier shall notify the covered  
5 person or the covered person's authorized representative,  
6 the independent review organization, and the commissioner in  
7 writing of its decision. The independent review organization  
8 shall terminate the external review upon receipt of notice  
9 of the health carrier's decision to reverse its adverse  
10 determination or final adverse determination.

11     12. In addition to the documents and information provided to  
12 the independent review organization pursuant to this section,  
13 the independent review organization shall, to the extent the  
14 information or documents are available and the independent  
15 review organization considers them appropriate, consider the  
16 following in reaching a decision:

17     *a.* The covered person's pertinent medical records.

18     *b.* The treating health care professional's recommendation.

19     *c.* Consulting reports from appropriate health care  
20 professionals and other documents submitted by the health  
21 carrier, covered person, or the covered person's treating  
22 physician or other health care professional.

23     *d.* The terms of coverage under the covered person's health  
24 benefit plan with the health carrier, to ensure that the  
25 independent review organization's decision is not contrary to  
26 the terms of coverage under the covered person's health benefit  
27 plan with the health carrier.

28     *e.* The most appropriate practice guidelines, which shall  
29 include applicable evidence-based standards and may include any  
30 other practice guidelines developed by the federal government,  
31 national or professional medical societies, boards, and  
32 associations.

33     *f.* Any applicable clinical review criteria developed and  
34 used by the health carrier.

35     *g.* The opinion of the independent review organization's

1 clinical reviewer after considering the information or  
2 documents described in paragraphs "a" through "f" to the extent  
3 the information or documents are available and the clinical  
4 reviewer considers them relevant.

5 13. a. Within forty-five days after the date of receipt  
6 of a request for an external review, the independent review  
7 organization shall provide written notice of its decision to  
8 uphold or reverse the adverse determination or final adverse  
9 determination of the health carrier to the covered person or  
10 the covered person's authorized representative, the health  
11 carrier, and the commissioner.

12 b. The independent review organization shall include in its  
13 decision all of the following:

14 (1) A general description of the reason for the request for  
15 external review.

16 (2) The date the independent review organization received  
17 the assignment from the commissioner to conduct the external  
18 review.

19 (3) The date the external review was conducted.

20 (4) The date of the decision.

21 (5) The principal reason or reasons for its decision,  
22 including what applicable evidence-based standards, if any,  
23 were a basis for its decision.

24 (6) The rationale for its decision.

25 (7) References to evidence or documentation, including  
26 evidence-based standards, considered in reaching its decision.

27 14. Upon receipt of notice of a decision reversing the  
28 adverse determination or final adverse determination of the  
29 health carrier, the health carrier shall immediately approve  
30 the coverage that was the subject of the determination.

31 Sec. 8. NEW SECTION. 514J.108 External review — expedited.

32 1. Notwithstanding section 514J.107, a covered person or  
33 the covered person's authorized representative may make an  
34 oral or written request to the commissioner for an expedited  
35 external review at the time the covered person or the covered

1 person's authorized representative receives any of the  
2 following:

3     *a.* An adverse determination that involves a medical  
4 condition of the covered person for which the time frame for  
5 completion of an internal review of a grievance involving an  
6 adverse determination would seriously jeopardize the life or  
7 health of the covered person or would jeopardize the covered  
8 person's ability to regain maximum function.

9     *b.* A final adverse determination that involves a medical  
10 condition where the time frame for completion of a standard  
11 external review would seriously jeopardize the life or health  
12 of the covered person or would jeopardize the covered person's  
13 ability to regain maximum function.

14     *c.* A final adverse determination that concerns an admission,  
15 availability of care, continued stay, or health care service  
16 for which the covered person received emergency services, and  
17 has not been discharged from a facility.

18     2. *a.* Upon receipt of a request for an expedited external  
19 review, the commissioner shall immediately send written notice  
20 of the request to the health carrier.

21     *b.* Immediately upon receipt of notice of a request for  
22 expedited external review, the health carrier shall complete  
23 a preliminary review of the request to determine whether the  
24 request meets the eligibility requirements for external review  
25 set forth in section 514J.107, subsection 3, and this section.

26     *c.* The health carrier shall then immediately issue a  
27 notice of initial determination informing the commissioner  
28 and the covered person or the covered person's authorized  
29 representative of its eligibility determination including  
30 a statement informing the covered person or the covered  
31 person's authorized representative of the right to appeal that  
32 determination to the commissioner.

33     *d.* The commissioner may specify by rule the form required  
34 for the health carrier's notice of initial determination and  
35 any supporting information to be included in the notice.

1 3. The commissioner may determine that a request is  
2 eligible for expedited external review, notwithstanding a  
3 health carrier's initial determination that the request is  
4 not eligible. In making a determination, the commissioner's  
5 decision shall be made in accordance with the terms of the  
6 covered person's health benefit plan and shall be subject to  
7 all applicable provisions of this chapter. The commissioner  
8 shall make a determination pursuant to this subsection as  
9 expeditiously as possible.

10 4. *a.* Upon receipt of notice from a health carrier  
11 that a request is eligible for expedited external review or  
12 upon a determination by the commissioner that a request is  
13 eligible for expedited external review, the commissioner shall  
14 immediately assign an independent review organization from the  
15 list of approved independent review organizations maintained by  
16 the commissioner to conduct the expedited external review. The  
17 commissioner shall then immediately notify the health carrier  
18 and the covered person or the covered person's authorized  
19 representative of the name of the assigned independent review  
20 organization.

21 *b.* The assignment of an independent review organization  
22 shall be done on a random basis among those approved  
23 independent review organizations qualified to conduct the  
24 particular external review based on the nature of the health  
25 care service that is the subject of the adverse determination  
26 or final adverse determination and other circumstances,  
27 including conflict of interest concerns.

28 5. Upon receiving notice of the independent review  
29 organization assigned to conduct the expedited external review,  
30 the health carrier shall provide or transmit all necessary  
31 documents and information considered in making the adverse  
32 determination or final adverse determination to the independent  
33 review organization electronically or by telephone or facsimile  
34 or any other available expeditious method.

35 6. The independent review organization is not bound

1 by any decisions or conclusions reached during the health  
2 carrier's internal grievance process. The independent review  
3 organization shall consider the documents and information  
4 provided by the health carrier, and to the extent the  
5 information or documents are available and the independent  
6 review organization considers them appropriate, shall consider  
7 the following in reaching a decision:

8     *a.* The covered person's pertinent medical records.

9     *b.* The treating health care professional's recommendation.

10    *c.* Consulting reports from appropriate health care  
11 professionals and other documents submitted by the health  
12 carrier, covered person or the covered person's authorized  
13 representative, or the covered person's treating physician or  
14 other health care professional.

15    *d.* The terms of coverage under the covered person's health  
16 benefit plan with the health carrier, to ensure that the  
17 independent review organization's decision is not contrary to  
18 the terms of coverage under the covered person's health benefit  
19 plan with the health carrier.

20    *e.* The most appropriate practice guidelines, which shall  
21 include applicable evidence-based standards and may include any  
22 other practice guidelines developed by the federal government,  
23 national or professional medical societies, boards, and  
24 associations.

25    *f.* Any applicable clinical review criteria developed and  
26 used by the health carrier.

27    *g.* The opinion of the independent review organization's  
28 clinical reviewer after considering the information or  
29 documents described in paragraphs "a" through "f" to the extent  
30 the information or documents are available and the clinical  
31 reviewer considers them relevant.

32    7. *a.* As expeditiously as the covered person's medical  
33 condition or circumstances require, but in no event more than  
34 seventy-two hours after the date of receipt of an eligible  
35 request for expedited external review, the assigned independent

1 review organization shall do all of the following:

2 (1) Make a decision to uphold or reverse the adverse  
3 determination or final adverse determination of the health  
4 carrier.

5 (2) Notify the covered person or the covered person's  
6 authorized representative, the health carrier, and the  
7 commissioner of its decision.

8 *b.* If the notice given by the independent review  
9 organization pursuant to paragraph "a" was not in writing,  
10 within forty-eight hours after providing that notice,  
11 the independent review organization shall provide written  
12 confirmation of the decision to the covered person or the  
13 covered person's authorized representative, the health carrier,  
14 and the commissioner that includes the information set forth in  
15 section 514J.107, subsection 13, paragraph "b".

16 *c.* Upon receipt of the notice of decision by an independent  
17 review organization pursuant to paragraph "a" reversing the  
18 adverse determination or final adverse determination, the  
19 health carrier shall immediately approve the coverage that  
20 was the subject of the adverse determination or final adverse  
21 determination.

22 **Sec. 9. NEW SECTION. 514J.109 External review of**  
23 **experimental or investigational treatment adverse determinations.**

24 1. Within four months after the date of receipt of a notice  
25 of an adverse determination or final adverse determination that  
26 involves a denial of coverage based on a determination that  
27 the health care service or treatment recommended or requested  
28 is experimental or investigational, a covered person or the  
29 covered person's authorized representative may file a request  
30 for external review with the commissioner.

31 2. Within one business day after the date of receipt of the  
32 request, the commissioner shall notify the health carrier of  
33 the request.

34 3. Within five business days following the date of receipt  
35 of notice of a request for external review pursuant to this

1 section, the health carrier shall complete a preliminary review  
2 of the request to determine whether:

3     *a.* The individual is or was a covered person under the  
4 health benefit plan at the time the health care service or  
5 treatment was recommended or requested.

6     *b.* The recommended or requested health care service or  
7 treatment that is the subject of the adverse determination or  
8 final adverse determination meets the following conditions:

9         (1) Is a covered benefit under the covered person's health  
10 benefit plan except for the health carrier's determination that  
11 the service or treatment is experimental or investigational for  
12 a particular medical condition.

13         (2) Is not explicitly listed as an excluded benefit under  
14 the covered person's health benefit plan with the health  
15 carrier.

16     *c.* The covered person's treating physician has certified  
17 that one of the following situations is applicable:

18         (1) Standard health care services or treatments have  
19 not been effective in improving the condition of the covered  
20 person.

21         (2) Standard health care services or treatments are not  
22 medically appropriate for the covered person.

23         (3) There is no available standard health care service or  
24 treatment covered by the health carrier that is more beneficial  
25 than the recommended or requested health care service or  
26 treatment sought.

27     *d.* The covered person's treating physician has certified in  
28 writing one of the following:

29         (1) That the recommended or requested health care service  
30 or treatment that is the subject of the adverse determination  
31 or final adverse determination is likely to be more beneficial  
32 to the covered person, in the physician's opinion, than any  
33 available standard health care services or treatments.

34         (2) The physician is a licensed, board-certified, or  
35 board-eligible physician qualified to practice in the area of

1 medicine appropriate to treat the covered person's condition,  
2 and that scientifically valid studies using accepted protocols  
3 demonstrate that the health care service or treatment  
4 recommended or requested that is the subject of the adverse  
5 determination or final adverse determination is likely to  
6 be more beneficial to the covered person than any available  
7 standard health care services or treatments.

8 e. The covered person or the covered person's authorized  
9 representative has exhausted the health carrier's internal  
10 grievance process, unless the covered person or the covered  
11 person's authorized representative is not required to exhaust  
12 the health carrier's internal grievance process pursuant to  
13 section 514J.106 or 514J.108.

14 f. The covered person or the covered person's authorized  
15 representative has provided all the information and forms  
16 required by the commissioner that are necessary to process an  
17 external review pursuant to this section.

18 4. Within one business day after completion of the  
19 preliminary review pursuant to subsection 3, the health  
20 carrier shall notify the commissioner and the covered person  
21 or the covered person's authorized representative in writing  
22 whether the request is complete and whether the request is  
23 eligible for external review pursuant to this section. If the  
24 request is not complete, the health carrier shall notify the  
25 commissioner and the covered person or the covered person's  
26 authorized representative in writing and include in the notice  
27 what information or materials are needed to make the request  
28 complete. If the request is not eligible for external review,  
29 the health carrier shall notify the covered person or the  
30 covered person's authorized representative and the commissioner  
31 in writing and include in the notice the reasons for its  
32 ineligibility.

33 5. The commissioner may specify by rule the form required  
34 for the health carrier's notice of initial determination and  
35 any supporting information to be included in the notice. The

1 notice of initial determination shall include a statement  
2 informing the covered person or the covered person's authorized  
3 representative that a health carrier's initial determination  
4 that the external review request is ineligible for review may  
5 be appealed to the commissioner.

6 6. The commissioner may determine that a request is eligible  
7 for external review pursuant to this section, notwithstanding  
8 a health carrier's initial determination that the request  
9 is ineligible, and require that it be referred for external  
10 review. In making this determination, the commissioner's  
11 decision shall be made in accordance with the terms of the  
12 covered person's health benefit plan and shall be subject to  
13 all applicable provisions of this chapter.

14 7. Within one business day after receipt of the notice  
15 from the health carrier that the external review request is  
16 eligible for external review or upon a determination by the  
17 commissioner that a request is eligible for external review,  
18 the commissioner shall do all of the following:

19 a. Assign an independent review organization from the list  
20 of approved independent review organizations maintained by the  
21 commissioner and notify the health carrier of the name of the  
22 assigned independent review organization.

23 b. Notify the covered person or the covered person's  
24 authorized representative in writing of the request's  
25 eligibility and acceptance for external review and the  
26 name of the assigned independent review organization and  
27 that the covered person or the covered person's authorized  
28 representative may submit in writing to the independent review  
29 organization, within five business days following the date  
30 of receipt of such notice, additional information that the  
31 independent review organization shall consider when conducting  
32 the external review. The independent review organization  
33 may, in the organization's discretion, accept and consider  
34 additional information submitted by the covered person or the  
35 covered person's authorized representative after five business

1 days.

2 8. Within one business day after receipt of the notice  
3 of assignment to conduct the external review, the assigned  
4 independent review organization shall select one or more  
5 clinical reviewers, as it determines is appropriate pursuant to  
6 subsection 9 to conduct the external review.

7 9. In selecting clinical reviewers, the independent review  
8 organization shall select physicians or other health care  
9 professionals who meet the minimum qualifications described in  
10 this chapter and, through clinical experience in the past three  
11 years, are experts in the treatment of the covered person's  
12 condition and knowledgeable about the recommended or requested  
13 health care service or treatment that is the subject of the  
14 adverse determination or the final adverse determination.  
15 Neither the covered person or the covered person's authorized  
16 representative nor the health carrier shall choose or control  
17 the choice of the clinical reviewers selected to conduct the  
18 external review.

19 10. Each clinical reviewer selected shall provide a written  
20 opinion to the independent review organization regarding  
21 whether the recommended or requested health care service or  
22 treatment should be covered. Each clinical reviewer shall  
23 review all of the information and documents received and any  
24 other information submitted in writing by the covered person or  
25 the covered person's authorized representative. In reaching  
26 an opinion, a clinical reviewer is not bound by any decisions  
27 or conclusions reached during the health carrier's internal  
28 grievance process.

29 11. Within five business days after receipt of notice of the  
30 assignment of the independent review organization, the health  
31 carrier shall provide to the independent review organization  
32 the documents and any information considered in making the  
33 adverse determination or the final adverse determination.  
34 Failure by the health carrier to provide the documents and  
35 information within the time specified shall not delay the

1 conduct of the external review.

2 12. If the health carrier fails to provide the documents  
3 and information within the time specified, the independent  
4 review organization may terminate the external review and  
5 make a decision to reverse the adverse determination or final  
6 adverse determination. Within one business day after making  
7 such a decision, the independent review organization shall  
8 notify the covered person or the covered person's authorized  
9 representative, the health carrier, and the commissioner.

10 13. Within one business day after the receipt of any  
11 information submitted by the covered person or the covered  
12 person's authorized representative, the independent review  
13 organization shall forward the information to the health  
14 carrier. Upon receipt of the forwarded information, the health  
15 carrier may reconsider its adverse determination or final  
16 adverse determination that is the subject of the external  
17 review.

18 a. Reconsideration by the health carrier of its adverse  
19 determination or final adverse determination shall not delay or  
20 terminate the external review. The external review shall only  
21 be terminated if the health carrier decides, upon completion  
22 of its reconsideration, to reverse its determination and  
23 provide coverage or payment for the recommended or requested  
24 health care service or treatment that is the subject of the  
25 determination.

26 b. Within one business day after making a decision to  
27 reverse its determination, the health carrier shall notify  
28 the covered person or the covered person's authorized  
29 representative, the independent review organization, and the  
30 commissioner in writing of its decision. The independent  
31 review organization shall terminate the external review upon  
32 receipt of such notice from the health carrier.

33 14. a. Within twenty days after being selected to conduct  
34 the external review, each clinical reviewer shall provide  
35 an opinion to the assigned independent review organization

1 regarding whether the recommended or requested health care  
2 service or treatment should be covered pursuant to this  
3 section.

4 *b.* Each clinical reviewer's opinion shall be in writing and  
5 include the following information:

6 (1) A description of the covered person's medical  
7 condition.

8 (2) A description of the indicators relevant to determining  
9 whether there is sufficient evidence to demonstrate that the  
10 recommended or requested health care service or treatment is  
11 likely to be more beneficial to the covered person than any  
12 available standard health care services or treatments and that  
13 the adverse risks of the recommended or requested health care  
14 service or treatment would not be substantially increased over  
15 those of available standard health care services or treatments.

16 (3) A description and analysis of any medical or scientific  
17 evidence considered in reaching the opinion.

18 (4) A description and analysis of any applicable  
19 evidence-based standards.

20 (5) Information on whether the reviewer's rationale for  
21 the opinion is based on either of the factors described in  
22 subsection 15, paragraph "e".

23 15. In addition to the documents and information provided,  
24 each clinical reviewer, to the extent the information or  
25 documents are available and the reviewer considers them  
26 appropriate, shall consider all of the following in reaching  
27 an opinion:

28 *a.* The covered person's pertinent medical records.

29 *b.* The treating physician's recommendation or request.

30 *c.* Consulting reports from appropriate health care  
31 professionals and other documents submitted by the health  
32 carrier, the covered person or the covered person's authorized  
33 representative, or the covered person's treating physician or  
34 other health care professional.

35 *d.* The terms of coverage under the covered person's health

1 benefit plan with the health carrier to ensure that, but  
2 for the health carrier's determination that the recommended  
3 or requested health care service or treatment that is the  
4 subject of the opinion is experimental or investigational, the  
5 reviewer's opinion is not contrary to the terms of coverage  
6 under the covered person's health benefit plan with the health  
7 carrier.

8 e. Whether either of the following factors is applicable:

9 (1) The recommended or requested health care service or  
10 treatment has been approved by the federal food and drug  
11 administration, if applicable, for the condition.

12 (2) Medical or scientific evidence or evidence-based  
13 standards demonstrate that the expected benefits of the  
14 recommended or requested health care service or treatment is  
15 likely to be more beneficial to the covered person than any  
16 available standard health care service or treatment and the  
17 adverse risks of the recommended or requested health care  
18 service or treatment would not be substantially increased over  
19 those of available standard health care services or treatments.

20 16. a. If a majority of the clinical reviewers opine that  
21 the recommended or requested health care service or treatment  
22 should be covered, the independent review organization shall  
23 make a decision to reverse the health carrier's adverse  
24 determination or final adverse determination.

25 b. If a majority of the clinical reviewers opine that the  
26 recommended or requested health care service or treatment  
27 should not be covered, the independent review organization  
28 shall make a decision to uphold the health carrier's adverse  
29 determination or final adverse determination.

30 c. If the clinical reviewers are evenly split as to whether  
31 the recommended or requested health care service or treatment  
32 should be covered, the independent review organization shall  
33 obtain the opinion of an additional clinical reviewer in order  
34 for the independent review organization to make a decision  
35 based on the opinions of a majority of the clinical reviewers.

1     *d.* The additional clinical reviewer selected shall use the  
2 same information to reach an opinion as the clinical reviewers  
3 who have already submitted their opinions.

4     *e.* The selection of an additional clinical reviewer under  
5 this subsection shall not extend the time within which the  
6 assigned independent review organization is required to make a  
7 decision based on the opinions of the clinical reviewers for  
8 the external review.

9     17. Within twenty days after it receives the opinion  
10 of each clinical reviewer, the assigned independent review  
11 organization shall make a decision based on the opinions of  
12 the clinical reviewer or reviewers, to uphold or reverse the  
13 adverse determination or final adverse determination of the  
14 health carrier and provide written notice of the decision  
15 to the covered person or the covered person's authorized  
16 representative, the health carrier, and the commissioner.

17     18. *a.* A covered person or the covered person's authorized  
18 representative may make a written or oral request to the  
19 commissioner for an expedited external review of the adverse  
20 determination or final adverse determination pursuant to  
21 this subsection if the covered person's treating physician  
22 certifies, in writing, that the recommended or requested  
23 health care service or treatment that is the subject of the  
24 request would be significantly less effective if not promptly  
25 initiated.

26     (1) Upon receipt of a request for an expedited external  
27 review pursuant to this subsection, the commissioner shall  
28 immediately notify the health carrier.

29     (2) Upon receipt of notice of the request for expedited  
30 external review, the health carrier shall immediately determine  
31 whether the request is eligible for external review as  
32 provided in subsection 3, paragraphs "a" through "f", and shall  
33 immediately issue a notice of initial determination informing  
34 the commissioner and the covered person or the covered person's  
35 authorized representative of its eligibility determination.

1 The notice of initial determination of eligibility issued by a  
2 health carrier shall include a statement informing the covered  
3 person or the covered person's authorized representative that  
4 the health carrier's initial determination that the external  
5 review request is ineligible for expedited external review may  
6 be appealed to the commissioner.

7 (3) The commissioner may determine that a request is  
8 eligible for external review, notwithstanding a health  
9 carrier's initial determination that the request is not  
10 eligible, and refer the request for external review. In making  
11 this determination, the commissioner's decision shall be made  
12 in accordance with the terms of the covered person's health  
13 benefit plan and shall be subject to all applicable provisions  
14 of this chapter.

15 b. (1) Upon receipt of the notice of initial determination  
16 that the request is eligible for expedited external review  
17 or upon a determination by the commissioner that the request  
18 is eligible for expedited external review, the commissioner  
19 shall immediately assign an independent review organization  
20 to conduct the expedited external review, from the list of  
21 approved independent review organizations maintained by the  
22 commissioner, and notify the health carrier of the name of the  
23 assigned independent review organization.

24 (2) Upon receipt of notice of the independent review  
25 organization assigned to conduct an expedited external review,  
26 the health carrier shall provide or transmit all necessary  
27 documents and information considered in making the adverse  
28 determination or final adverse determination to the independent  
29 review organization electronically or by telephone or facsimile  
30 or any other available expeditious method.

31 (3) A clinical reviewer or clinical reviewers shall be  
32 selected immediately by the independent review organization and  
33 shall provide an opinion orally or in writing to the assigned  
34 independent review organization as expeditiously as the covered  
35 person's medical condition or circumstances require, but in no

1 event more than five calendar days after being selected. If  
2 the opinion provided was not in writing, within forty-eight  
3 hours following the date the opinion was provided, the clinical  
4 reviewer shall provide written confirmation of the opinion to  
5 the assigned independent review organization and include all  
6 required information in support of the opinion.

7 c. Within forty-eight hours after the date of receipt  
8 of the opinion of each clinical reviewer, the assigned  
9 independent review organization shall make a decision based  
10 on the opinions of the clinical reviewer or reviewers as to  
11 whether to reverse or uphold the adverse determination or  
12 final adverse determination and provide notice of the decision  
13 orally or in writing to the covered person or the covered  
14 person's authorized representative, the health carrier, and  
15 the commissioner. If the notice was provided orally, within  
16 forty-eight hours after the date of providing that notice,  
17 the independent review organization shall provide written  
18 confirmation of the decision to the covered person or the  
19 covered person's authorized representative, the health carrier,  
20 and the commissioner.

21 d. The independent review organization shall include in the  
22 notice of its decision all of the following:

23 (1) A general description of the reason for the request for  
24 an expedited external review.

25 (2) The written opinion of each clinical reviewer,  
26 including the recommendation of each clinical reviewer as  
27 to whether the recommended or requested health care service  
28 or treatment should be covered and the rationale for the  
29 reviewer's recommendation.

30 (3) The date the independent review organization was  
31 assigned by the commissioner to conduct the expedited external  
32 review.

33 (4) The date the expedited external review was conducted.

34 (5) The date of its decision.

35 (6) The principal reason or reasons for its decision.

1 (7) The rationale for its decision.

2 19. Upon receipt of notice of a decision of the independent  
3 review organization reversing an adverse determination or final  
4 adverse determination, the health carrier shall immediately  
5 approve coverage of the recommended or requested health care  
6 service or treatment that was the subject of the determination.

7 Sec. 10. NEW SECTION. 514J.110 **Effect of external review**  
8 **decision.**

9 1. An external review decision pursuant to this chapter is  
10 binding on the health carrier except to the extent the health  
11 carrier has other remedies available under applicable Iowa law.  
12 The external review process shall not be considered a contested  
13 case under chapter 17A.

14 2. *a.* A covered person or the covered person's authorized  
15 representative may appeal the external review decision made by  
16 an independent review organization by filing a petition for  
17 judicial review either in Polk county district court or in  
18 the district court in the county in which the covered person  
19 resides. The petition for judicial review must be filed  
20 within fifteen business days after the issuance of the review  
21 decision. The petition shall name the covered person or the  
22 covered person's authorized representative, or the person's  
23 health care provider as the petitioner. The respondent  
24 shall be the health carrier. The petition shall not name the  
25 independent review organization as a party.

26 *b.* The commissioner shall not be named as a respondent  
27 unless the petitioner alleges action or inaction by the  
28 commissioner under the standards articulated in section  
29 17A.19, subsection 10. Allegations against the commissioner  
30 under section 17A.19, subsection 10, shall be stated with  
31 particularity. The commissioner may, upon motion, intervene in  
32 the judicial review proceeding. The findings of fact by the  
33 independent review organization conducting the external review  
34 are conclusive and binding on appeal.

35 3. The health carrier shall follow and comply with the

1 decision of the court on appeal. The health carrier or  
2 treating health care provider shall not be subject to any  
3 penalties, sanctions, or award of damages for following and  
4 complying in good faith with the external review decision of  
5 the independent review organization or the decision of the  
6 court on appeal.

7 4. The covered person or the covered person's authorized  
8 representative may bring an action in Polk county district  
9 court or in the district court in the county in which the  
10 covered person resides to enforce the external review decision  
11 of the independent review organization or the decision of the  
12 court on appeal.

13 5. A covered person or the covered person's authorized  
14 representative shall not file a subsequent request for external  
15 review involving any determination for which the covered person  
16 or the covered person's authorized representative has already  
17 received an external review decision.

18 6. If a covered person dies before the completion of  
19 the external review process, the process shall continue to  
20 completion if there is potential liability of a health carrier  
21 to the estate of the covered person.

22 7. *a.* If a covered person who has already received health  
23 care services under a health benefit plan requests external  
24 review of the plan's adverse determination or final adverse  
25 determination and changes to another health benefit plan before  
26 the external review process is completed, the health carrier  
27 whose coverage was in effect at the time the health care  
28 service was received is responsible for completing the external  
29 review process.

30 *b.* If a covered person who has not yet received health  
31 care services requests external review of a health benefit  
32 plan's adverse determination or final adverse determination  
33 and then changes to another plan prior to receipt of the  
34 health care services and completion of the external review  
35 process, the external review process shall begin anew with the

1 covered person's current health carrier. In this instance,  
2 the external review process shall be conducted as an expedited  
3 external review.

4 Sec. 11. NEW SECTION. 514J.111 **Approval of independent**  
5 **review organizations.**

6 1. The commissioner shall approve applications submitted by  
7 independent review organizations to conduct external reviews  
8 under this chapter. The commissioner may retain an outside  
9 expert to perform reviews of such applications.

10 2. In order to be eligible for approval by the commissioner  
11 to conduct external reviews, an independent review organization  
12 shall meet all of the following requirements:

13 a. Be accredited by a nationally recognized private  
14 accrediting entity that the commissioner determines has  
15 independent review organization accreditation standards that  
16 are equivalent to or exceed the minimum qualifications for  
17 independent review organizations established in this chapter.

18 b. Submit an application in a form and format as directed by  
19 the commissioner.

20 c. Meet the minimum qualifications contained in section  
21 514J.112.

22 3. The commissioner may approve independent review  
23 organizations that are not accredited by a nationally  
24 recognized private accrediting entity if there are no  
25 acceptable nationally recognized private accrediting entities  
26 providing independent review organization accreditation.

27 4. The commissioner shall develop an application form for  
28 initially approving and for reapproving independent review  
29 organizations to conduct external reviews.

30 5. The commissioner may charge an initial application fee  
31 and a renewal fee as specified by rule.

32 6. The approval of an independent review organization to  
33 conduct external reviews by the commissioner pursuant to this  
34 chapter is effective for two years, unless the commissioner  
35 determines that the independent review organization is not

1 satisfying the minimum qualifications of this chapter. If the  
2 commissioner determines that an independent review organization  
3 has lost its accreditation or no longer satisfies the minimum  
4 requirements established under this chapter, the commissioner  
5 shall terminate approval of the independent review organization  
6 to conduct external reviews and remove the independent review  
7 organization from the list of independent review organizations  
8 approved to conduct external reviews that is maintained by the  
9 commissioner.

10 7. The commissioner shall maintain a list of currently  
11 approved independent review organizations.

12 Sec. 12. NEW SECTION. 514J.112 **Minimum qualifications for**  
13 **independent review organizations.**

14 1. To be approved to conduct external reviews pursuant  
15 to this chapter, an independent review organization shall  
16 have and maintain written policies and procedures that govern  
17 all aspects of both the standard external review process and  
18 the expedited external review process and that include, at a  
19 minimum, all of the following:

20 a. A quality assurance mechanism that does all of the  
21 following:

22 (1) Ensures that external reviews are conducted within the  
23 specified time frames and that required notices are provided  
24 in a timely manner.

25 (2) Ensures the selection of qualified and impartial  
26 clinical reviewers to conduct external reviews on behalf of  
27 the independent review organization and suitable matching of  
28 reviewers to specific cases and that the independent review  
29 organization employs or contracts with an adequate number of  
30 clinical reviewers to meet this objective.

31 (3) Ensures the confidentiality of medical and treatment  
32 records and clinical review criteria.

33 (4) Establishes and maintains written procedures to  
34 ensure that the independent review organization is unbiased in  
35 addition to any other procedures required under this section.

1 (5) Ensures that any person employed by or under contract  
2 with the independent review organization adheres to the  
3 requirements of this chapter.

4 *b.* A toll-free telephone service to receive information  
5 related to external reviews twenty-four hours a day, seven days  
6 a week, that is capable of accepting, recording, or providing  
7 appropriate instruction to incoming telephone callers outside  
8 normal business hours.

9 *c.* An agreement and a system to maintain required records  
10 and provide access to those records by the commissioner.

11 2. Each clinical reviewer assigned by an independent review  
12 organization to conduct external reviews shall be a physician  
13 or other appropriate health care professional who meets all of  
14 the following minimum qualifications:

15 *a.* Is an expert in the treatment of the covered person's  
16 medical condition that is the subject of the external review.

17 *b.* Is knowledgeable about the recommended or requested  
18 health care service or treatment through recent or current  
19 actual clinical experience treating patients with the same or  
20 similar medical condition as the covered person.

21 *c.* Holds a nonrestricted license in a state of the United  
22 States and, for physicians, a current certification by a  
23 recognized American medical specialty board in the area or  
24 areas appropriate to the subject of the external review.

25 *d.* Has no history of disciplinary actions or sanctions,  
26 including loss of staff privileges or participation  
27 restrictions, that have been taken or are pending by any  
28 hospital, governmental agency or unit, or regulatory body that  
29 raise a substantial question as to the clinical reviewer's  
30 physical, mental, or professional competence or moral  
31 character.

32 3. An independent review organization shall not own  
33 or control, be a subsidiary of, or in any way be owned or  
34 controlled by, or exercise control with, a health benefit plan,  
35 a national, state, or local trade association of health benefit

1 plans, or a national, state, or local trade association of  
2 health care providers.

3 4. Neither the independent review organization selected to  
4 conduct an external review nor any clinical reviewer assigned  
5 by the independent organization to conduct an external review  
6 shall have a material professional, familial, or financial  
7 conflict of interest with any of the following:

8 a. The health carrier that is the subject of the external  
9 review.

10 b. The covered person whose health care service or treatment  
11 is the subject of the external review or the covered person's  
12 authorized representative.

13 c. Any officer, director, or management employee of the  
14 health carrier that is the subject of the external review.

15 d. The health care professional or the health care  
16 professional's medical group or independent practice  
17 association recommending the health care service or treatment  
18 that is the subject of the external review.

19 e. The facility at which the recommended health care service  
20 or treatment would be provided.

21 f. The developer or manufacturer of the principal drug,  
22 device, procedure, or other therapy being recommended for the  
23 covered person whose health care service treatment is the  
24 subject of the external review.

25 5. In determining whether an independent review  
26 organization or a clinical reviewer of the independent  
27 review organization has a material professional, familial,  
28 or financial conflict of interest as provided in subsection  
29 4, the commissioner shall take into consideration situations  
30 where the independent review organization to be assigned to  
31 conduct an external review of a specified case or a clinical  
32 reviewer to be assigned by the independent review organization  
33 to conduct an external review of a specified case may have an  
34 apparent professional, familial, or financial relationship or  
35 connection with a person described in subsection 4, but the

1 characteristics of that relationship or connection are such  
2 that they do not constitute a material professional, familial,  
3 or financial conflict of interest that would prohibit selection  
4 of the independent review organization or the clinical reviewer  
5 to conduct the external review.

6 6. a. An independent review organization that is accredited  
7 by a nationally recognized private accrediting entity that  
8 has independent review accreditation standards that the  
9 commissioner has determined are equivalent to or exceed the  
10 minimum qualifications of this section shall be presumed to be  
11 in compliance with the requirements of this section.

12 b. The commissioner shall initially and periodically review  
13 the standards of each nationally recognized private accrediting  
14 entity that provides accreditation to independent review  
15 organizations to determine whether the accrediting entity's  
16 standards are, and continue to be, equivalent to or exceed the  
17 minimum qualifications established under this section. The  
18 commissioner may accept a review of those standards conducted  
19 by the national association of insurance commissioners for the  
20 purpose of making a determination under this subsection.

21 c. Upon request, a nationally recognized private accrediting  
22 entity shall make its current independent review organization  
23 accreditation standards available to the commissioner or  
24 to the national association of insurance commissioners in  
25 order for the commissioner to determine if the accrediting  
26 entity's standards are equivalent to or exceed the minimum  
27 qualifications established under this section. The  
28 commissioner may exclude consideration of accreditation of  
29 independent review organizations by any private accrediting  
30 entity whose standards have not been reviewed by the national  
31 association of insurance commissioners.

32 Sec. 13. NEW SECTION. 514J.113 Immunity for independent  
33 review organizations.

34 An independent review organization, a clinical reviewer  
35 working on behalf of an independent review organization, or

1 an employee, agent, or contractor of an independent review  
2 organization shall not be liable in damages to any person for  
3 any opinions rendered or acts or omissions performed within the  
4 scope of the duties of the organization, the clinical reviewer,  
5 or an employee, agent, or contractor of the organization under  
6 this chapter during, or upon completion of, an external review  
7 conducted pursuant to this chapter, unless the opinion was  
8 rendered or the act or omission was performed in bad faith or  
9 involved gross negligence.

10 Sec. 14. NEW SECTION. 514J.114 External review reporting  
11 requirements.

12 1. a. An independent review organization assigned to  
13 conduct an external review shall maintain written records in  
14 the aggregate by state and by health carrier of all requests  
15 for external review for which it conducted an external review  
16 during a calendar year.

17 b. Each independent review organization required to maintain  
18 written records pursuant to this section shall submit to the  
19 commissioner, upon request, a report in the format specified by  
20 the commissioner. The report shall include in the aggregate by  
21 state and by health carrier all of the following:

22 (1) The total number of requests for external review  
23 assigned to the independent review organization.

24 (2) The average length of time for resolution of each  
25 request for external review assigned to the independent review  
26 organization.

27 (3) A summary of the types of coverages or cases for which  
28 an external review was requested, in the format required by the  
29 commissioner by rule.

30 (4) Any other information required by the commissioner.

31 c. The independent review organization shall retain the  
32 written records for at least three years.

33 2. a. Each health carrier shall maintain written records  
34 in the aggregate by state and by type of health benefit plan  
35 offered by the health carrier of all requests for external

1 review that the health carrier receives notice of from the  
2 commissioner pursuant to this chapter.

3     *b.* Each health carrier required to maintain written records  
4 of requests for external review pursuant to this subsection  
5 shall submit to the commissioner, upon request, a report in the  
6 format specified by the commissioner. The report shall include  
7 in the aggregate by state and by type of health benefit plan  
8 offered all of the following:

9       (1) The total number of requests for external review of  
10 the health carrier's adverse determinations and final adverse  
11 determinations.

12       (2) Of the total number of requests for external review, the  
13 number of requests determined eligible for external review.

14       (3) The number of requests for external review resolved  
15 and, of those resolved, the number resolved upholding the  
16 adverse determination or final adverse determination of the  
17 health carrier and the number resolved reversing the adverse  
18 determination or final adverse determination of the health  
19 carrier.

20       (4) The number of external reviews that were terminated as  
21 the result of a reconsideration by the health carrier of its  
22 adverse determination or final adverse determination after the  
23 receipt of additional information from the covered person or  
24 the covered person's authorized representative.

25       (5) Any other information the commissioner may request or  
26 require.

27     *c.* The health carrier shall retain the written records for  
28 at least three years.

29     Sec. 15. NEW SECTION. 514J.115 **Expenses of external review.**

30     The health carrier against which a request for a standard  
31 external review or an expedited external review is filed shall  
32 pay the costs of retaining an independent review organization  
33 to conduct the external review.

34     Sec. 16. NEW SECTION. 514J.116 **Disclosure requirements.**

35     1. Each health carrier shall include a description of

1 the external review procedures contained in this chapter in  
2 or attached to any policy, certificate, membership booklet,  
3 outline of coverage, or other evidence of coverage that is  
4 provided to a covered person. The description shall be in a  
5 format prescribed by the commissioner by rule.

6 2. The description required by subsection 1 shall include  
7 a statement that informs the covered person of the right of  
8 the covered person to file a request for an external review  
9 of an adverse determination or final adverse determination of  
10 the health carrier with the commissioner. The statement shall  
11 explain that external review is available when the adverse  
12 determination or final adverse determination involves an issue  
13 of medical necessity, appropriateness, health care setting,  
14 level of care, or effectiveness. The statement shall include  
15 the telephone number and address of the commissioner. The  
16 statement shall also inform the covered person that when filing  
17 a request for external review, the covered person will be  
18 required to authorize the release of any medical records of  
19 the covered person that may be required to be reviewed for the  
20 purpose of reaching a decision on the request for external  
21 review.

22 Sec. 17. NEW SECTION. 514J.117 **Rulemaking authority.**

23 The commissioner may adopt rules pursuant to chapter 17A to  
24 carry out the provisions of this chapter.

25 Sec. 18. NEW SECTION. 514J.118 **Severability.**

26 If any provision of this chapter, or the application of the  
27 provision to any person or circumstance is held invalid, the  
28 remainder of the chapter, and the application of the provision  
29 to persons or circumstances other than those to which it is  
30 held invalid, shall not be affected.

31 Sec. 19. NEW SECTION. 514J.119 **Penalties.**

32 A person who fails to comply with the provisions of this  
33 chapter or the rules adopted pursuant to this chapter is  
34 subject to the penalties provided under chapter 507B.

35 Sec. 20. NEW SECTION. 514J.120 **Applicability.**

1 1. This chapter applies to all requests for external review  
2 filed on or after July 1, 2011.

3 2. Section 514J.116 applies to all health benefit plans  
4 delivered, issued for delivery, continued, or renewed in this  
5 state on or after July 1, 2011.

6 Sec. 21. REPEAL. Sections 514J.1 through 514J.15, Code  
7 2011, are repealed.

8 Sec. 22. TRANSITION PROVISION — APPLICABILITY TO PRIOR  
9 REQUESTS. Sections 514J.1 through 514J.15, Code 2011, are  
10 applicable to all requests for external review filed prior to  
11 July 1, 2011.

12 EXPLANATION

13 This bill adds new provisions in Code chapter 514J,  
14 which provides procedures for external review of adverse  
15 determinations made by health carriers, as required by the  
16 federal Patient Protection and Affordable Care Act, as amended  
17 by the federal Health Care and Education Reconciliation Act  
18 of 2010, which amends the Public Health Service Act. The new  
19 provisions apply to all requests for external review filed on  
20 or after July 1, 2011. The bill repeals the current provisions  
21 in Code chapter 514J relating to the external review of health  
22 care coverage decisions.

23 An "adverse determination" is a determination by a health  
24 carrier that payment for a health care service that is a  
25 covered benefit under a health benefit plan is being denied,  
26 reduced, or terminated because the health care service does  
27 not meet the carrier's requirements for medical necessity,  
28 appropriateness, health care setting, level of care, or  
29 effectiveness. A "final adverse determination" is an adverse  
30 determination involving a covered benefit that has been upheld  
31 by a health carrier at the completion of the health carrier's  
32 internal grievance process.

33 The bill allows a covered person under a health benefit plan  
34 or the covered person's authorized representative to request  
35 an external review of the health carrier's determination after

1 receiving a final adverse determination or sooner, after  
2 receiving an adverse determination, if the covered person has  
3 a medical condition where the time frame for completion of  
4 that internal review would jeopardize the person's life or  
5 health or ability to regain maximum function, or the adverse  
6 determination is that the requested health care service is  
7 experimental or investigational and the effectiveness of the  
8 treatment will be significantly less effective if not promptly  
9 initiated. The bill provides procedures for a standard  
10 external review or an expedited external review.

11 Pursuant to a request for standard external review, the  
12 health carrier must complete a preliminary review to determine  
13 if the request is eligible for external review as specified in  
14 the bill and report to the commissioner of insurance and the  
15 covered person. Even if the health carrier determines that  
16 the request is ineligible, the commissioner of insurance may  
17 determine that the request is eligible for review.

18 Once a request is determined to be eligible for review,  
19 the commissioner is required to assign an independent review  
20 organization to conduct the external review of the adverse or  
21 final adverse determination of the health carrier. During the  
22 review, the carrier may reconsider its adverse or final adverse  
23 determination and provide the coverage requested. If this does  
24 not occur, the independent review organization selects clinical  
25 reviewers to consider all pertinent information and within  
26 45 days of receiving the request for external review, the  
27 independent review organization must provide written notice of  
28 its decision to uphold or reverse the adverse or final adverse  
29 determination of the carrier. Upon receipt of a decision of  
30 reversal, the carrier must approve the coverage that was the  
31 subject of the adverse or final adverse determination.

32 The bill also provides a similar procedure for expedited  
33 external review of an adverse or final adverse determination  
34 that involves a medical condition of the covered person for  
35 which the time frame for completion of the internal review

1 by the health carrier or a standard external review would  
2 seriously jeopardize the life or health or the ability to  
3 regain maximum function of the covered person. The expedited  
4 external review procedures provide that a request for expedited  
5 external review can be made by a covered person orally,  
6 and shortens the required time frames for action by the  
7 health carrier, the commissioner, and the independent review  
8 organization in responding to the request and reaching a  
9 decision.

10 The bill provides separate procedures for standard and  
11 expedited external reviews of adverse determinations or  
12 final adverse determinations involving experimental or  
13 investigational treatment. In a standard external review, if  
14 an independent review organization selects multiple clinical  
15 reviewers to review the request, the organization must make  
16 a decision to uphold or reverse an adverse or final adverse  
17 determination of a health carrier based on the opinion of a  
18 majority of the clinical reviewers.

19 The bill allows a covered person or the covered person's  
20 authorized representative to appeal the external review  
21 decision made by an independent review organization by filing a  
22 petition for judicial review in Polk county district court or  
23 in the district court in the county where the covered person  
24 resides. Findings of fact made by an independent review  
25 organization are conclusive and binding on appeal. A covered  
26 person or the covered person's authorized representative may  
27 also bring an action in district court to enforce an external  
28 review decision against a carrier.

29 The bill includes requirements for the qualifications of an  
30 independent review organization to be listed as eligible for  
31 selection by the commissioner to conduct an external review.

32 The bill provides that independent review organizations and  
33 clinical reviewers are not liable in damages for any opinions  
34 rendered in furtherance of their duties under this new division  
35 unless rendered in bad faith or with gross negligence.

1 Independent review organizations and health carriers are  
2 required to keep specified records about external review  
3 requests involving them. The expense of retaining an  
4 independent review organization to conduct an external review  
5 is assessed against the health carrier whose adverse or final  
6 adverse determination is being reviewed.

7 External review procedures must be disclosed by health  
8 carriers by including or attaching them to the policies,  
9 certificates, membership booklets, outline of coverage, or  
10 other evidence of coverage that is provided to covered persons.  
11 This disclosure requirement applies to all health benefit plans  
12 delivered, issued for delivery, continued, or renewed on or  
13 after July 1, 2011.

14 The commissioner of insurance has the authority to adopt  
15 rules to carry out the provisions of the new division and the  
16 provisions of the new division are severable if held invalid.